UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	CIVIL ACTION: 01-CV-12257PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris
	Chief Magistrate Judge Marian B. Bowler

DEFENDANT SICOR INC. AND SICOR PHARMACEUTICALS, INC.'S OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL HHS ASP DOCUMENTS

REQUEST FOR ORAL ARGUMENT

Defendants Sicor, Inc. and Sicor Pharmaceuticals, Inc. (collectively, "Sicor") respectfully file their brief in opposition to Plaintiffs' Motion to Compel HHS ASP Documents ("Motion to Compel"). Plaintiffs' Motion to Compel should be denied because their discovery requests are not reasonably calculated to lead to the discovery of admissible evidence and are therefore unduly burdensome.

I. BACKGROUND

On February 24, 2004, Judge Saris issued an opinion granting, in part, and denying, in part, Defendants' Motion to Dismiss the Amended Master Consolidated Complaint in this consolidated putative class action. *See In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 307 F. Supp.2d 196 (D. Mass. 2004).

Thereafter, on March 25, 2004, the Court issued Case Management Order No. 10 ("CMO 10"), allowing discovery "with respect to all parties, claims and issues not dismissed under the February 24, 2004 Memorandum and Order." However, in an effort to bring structure to the pretrial process in this "massive proposed class action" (*In re AWP*, 307 F. Supp. 2d at 201), CMO 10 also set forth a two-tiered discovery plan that created two groups of defendants. The

so-called "fast track" or "Track One" defendants consist of defendants AstraZeneca, the BMS Group, the GSK Group, the Johnson and Johnson Group and the Schering- Plough Group. The remaining "regular track" defendants, including Sicor, are subject to the "Phase Two" timetable.[1] CMO 10 at 4. Under CMO 10, all phases of the case through summary judgment will proceed first with respect to Track One defendants. CMO 10 at 1.

On March 31, 2004, in conflict with the timetable set forth in CMO 10, Plaintiffs served all Track One and Track Two defendants, including Sicor, with eighty-two "Omnibus" Requests for Production of Documents and Interrogatories requesting detailed information concerning pricing for each of the drugs at issue in this consolidated action. *See* Exhibit A, attached. Sicor timely objected to the Plaintiffs' premature efforts to obtain discovery, but in the spirit of cooperation and to facilitate exposure of Plaintiffs' meritless claims, Sicor produced documents responsive to Plaintiffs' Ominbus Requests prior to the timetable set forth in CMO 10 for Track Two defendants, while fully preserving all of its objections to such requests, including the fact that such requests are premature.[2] *See* Ex. A at 1, General Objection No. 1. Indeed, Sicor has expended extensive resources to locate, review and produce many thousands of pages of responsive documents.

On May 26, 2004, Plaintiffs served Sicor and all other defendants with a second set of document requests targeted at Average Sale Prices ("ASPs") (the "ASP Requests"). Sicor timely objected to these ASP Requests. *See* Exhibit B, attached. However, contrary to the Declaration of Steven W. Berman Filed in Support of Plaintiffs' Motion to Compel the Production of HHS ASP Documents, filed concurrently with Plaintiffs' Motion to Compel, neither Mr. Berman, nor

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[1] Judge Saris did order all defendants to *supplement* their prior document productions to include documents concerning AWP matters which were provided to or subpoenaed by certain governmental entities (CMO 10 at 1-2). Sicor provided this information on April 26, 2004.

[2] Sicor produced its first set of responsive documents of June 16, 2004, followed by a second production on June 30, 2004. Sicor's production efforts are on-going.

any other Plaintiffs' representative, contacted counsel for Sicor in an attempt to meet and confer prior to filing Plaintiffs' Motion to Compel. *See* LR, D. Mass. 7.1(a)(2).

As set forth more fully below, the Court should deny Plaintiffs' Motion to Compel because the ASP Requests are not reasonably calculated to lead to the discovery of admissible evidence and Sicor's ASP data is a confidential, proprietary trade secret that enjoys statutory protection under federal law.

II. ARGUMENT

A. The ASP Requests Are Not Reasonably Calculated To Lead To The Discovery Of Admissible Evidence.

The Plaintiffs' claim that their ASP Requests are relevant to class certification and liability issues (Pls.' Mem. at 2).[3] This argument is without merit. As a preliminary matter, Plaintiffs have not even attempted to explain how their ASP Requests are relevant to class certification issues, which typically involve questions of the size of the putative class, whether common issues of law and fact exist on a class-wide basis, whether the claims and defenses of representative parties are typical of those of the class and whether the proposed class representatives will fairly and adequately protect the interests of the class. *See generally* Fed. R. Civ. P. 23 (a). In the context of discovery, a general allegation of relevancy is insufficient to overcome specific objections by an adverse party. *See Gagne v. Reddy*, 104 F.R.D. 454, 456 n.4 (D. Mass 1984). Accordingly, Plaintiffs' bald assertions as to the relevancy of ASP information to class certification issues must be rejected.

Plaintiffs' assertion that the requested ASP information is relevant to liability issues in this case must also be rejected because it is factually flawed and inconsistent with any viable

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[3] All references to Plaintiffs' Memorandum in Support of Motion to Compel HHS ASP Documents are herein referred to using the abbreviation "Pls.' Mem. at __."

theory of liability or damages in this case. A careful review of the Medicare Interim Regulations, together with Plaintiffs' own definition of ASP reveals the fallacy of this assertion.

1. Plaintiffs' Cannot Establish The Relevancy Of Their Requests Because ASP As The New Benchmark For Medicare Reimbursement Is Indefinite And Subject to Change.

In December of 2003, Congress passed the Medicare Prescription Drug Improvement and Modernization Act (the "2003 Medicare Modernization Act" or the "MMA"). Specifically, the MMA creates a new prescription drug reimbursement protocol in which ASP replaces AWP as the pricing benchmark for pharmaceutical reimbursement under Medicare Part B as of January 1, 2005. *See* 2003 Medicare Modernization Act, § 303. The Act loosely describes ASP as the average of the final manufacturer's sales price to all U.S. purchasers, including rebates and other discounts. *See* 2003 Medicare Modernization Act § 303(c). However, the precise calculation method for ASP is still under active regulatory consideration by CMS, rendering a precise definition of ASP impossible at this time.

In the meantime, CMS has issued a "final interim rule" (the "Interim Medicare Regulations") in order to provide guidance to manufacturers as to how to calculate ASP until such time as a final rule is promulgated. *See* Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals, 69 Fed. Reg. 17935 (April 6, 2004). As of the date of this filing, no final rule has been issued and, according to CMS, the Interim Medicare Regulations may be modified in the future as "[CMS] gains more experience with the ASP System." 69 Fed. Reg. 17936. All of this activity highlights the fluid and unsettled aura surrounding "ASP."

Furthermore, in enacting the MMA, Congress acknowledged the confidential and highly sensitive proprietary trade secret nature of information elicited under the new ASP reporting requirements by extending confidentiality provisions applicable to similar pricing information

(*e.g.* AMP, "Best Price") to ASP information provided by drug manufacturers pursuant to the MMA.[4] *See* 42 U.S.C. § 1396r-8(b)(3)(D). In so doing, Congress expressed its plain intent that compliance with the MMA's new ASP reporting requirements would not impose a hardship upon pharmaceutical manufactures in the form of unfettered public access to their sensitive and proprietary information. Yet, that is exactly what Plaintiffs hope to achieve through the instant motion.

The disclosure of Sicor's confidential and proprietary ASP information is especially unwarranted in this instance because Plaintiffs' ASP Requests seek information provided pursuant to regulations which are novel, temporary and subject to further review and revision. Consequently, *current* ASP data is not probative of alleged "past spreads" or of alleged "prior AWP abuse." Pls. Mem. at 3. The Interim Medicare Regulations, moreover, did not even exist during the time period covered by the allegations of the Amended Master Consolidated Complaint ("AMCC"). At this juncture Plaintiffs have not and *cannot* meet their burden to demonstrate that the highly sensitive and confidential information they seek is reasonably calculated to lead to the discovery of admissible evidence as required under Federal Rule of Civil Procedure 26. Plaintiffs' Motion to Compel must therefore be denied.

2. Neither The Allegations of the Complaint, Nor Judge Saris' Prior Rulings Support ASP As Relevant In Determining AWP Or The Alleged Spread.

Sicor's compliance with new Congressional requirements to calculate ASP for the government does not magically make Plaintiffs' requests relevant. On the contrary, relevancy depends upon some relationship between the information sought and the claims and defenses at issue. something that is woefully lacking here. *See generally* Fed. R. Civ. P 26 (b)(1). Throughout the history of this litigation, Plaintiffs' have based their claims on the defendants'

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[4] The MMA amends the Medicaid Drug Rebate statute to add ASP to the manufacturer price reporting provisions at 42 U.S.C. § 1396r-8(b)(3)(A)(iii).

alleged manipulation and abuse of average *wholesale* price as the benchmark for reimbursement for prescription drugs under Medicare Part B. Moreover, Judge Saris has nowhere held that ASP is relevant to a determination of AWP.

Plaintiffs have previously relied on WAC in their liability and damages allegations. Judge Saris' opinion clearly references Plaintiffs' representations concerning these allegations. S*ee In re AWP*, 307 F. Supp.2d at 211-212 (*citing* AMCC at ¶¶544, 591). Having proffered WAC as their Rosetta Stone, Plaintiffs should not be permitted to change theories of liability mid-stream. Such fickleness is evidence of the lack of logical consistency in Plaintiffs' theories.

3. ASP and AWP Are Not Interchangeable

As discussed above, Plaintiffs have alleged WAC as the most accurate measure of AWP and the "spread." For this reason, the ASP Requests are both irrelevant and burdensome, since ASP is not a substitute for WAC or AWP, and thus cannot be used to determine AWP or the alleged AWP spread. Simply put, ASP is neither AWP nor WAC.

Given the lack of any meaningful connection between ASP and AWP, the Court should deny Plaintiffs' Motion to Compel. In *L. Knife & Son, Inc. v. Banfi Prods. Corp.*, 118 F.R.D. 269, 273 (D. Mass. 1987), the district court overruled a Special Master's ruling allowing discovery based on what the court found to be a faulty method of calculating damages. There, the antitrust plaintiff sought to establish damages in a case involving the alleged tying of wine purchases to transatlantic freight plus insurance using a "cost allocation" theory of damages. *See L. Knife & Sons.* ,118 F.R.D. at 270. Plaintiffs sought discovery of detailed cost figures for wine, freight and other expenses associated with the production of Riunite wine to support their damages claim. Finding the cost allocation approach to be "purely artificial" and noting that the plaintiffs had "failed to explain the connection between cost and market value or give any indication as to how that value can be determined from the information sought," the Court

rejected the plaintiffs' cost allocation theory in favor of a fair market value approach. *Id.* at 271. The Court then held that the lack of relevance of the information sought by the plaintiff rendered the discovery requests unduly burdensome within the meaning of Rule 26. *See id.* at 273.

The instant case fits squarely within the court's reasoning in *L. Knife & Sons*. Contrary to Plaintiffs' argument, (Pls.' Mem. at 2-3), the ASP information sought by the Plaintiffs has no relevance in determining AWP or the alleged AWP "spread," which according to the Plaintiffs is determined by reference to WAC.

In their Omnibus Requests, Plaintiffs defined ASP as "the price after reflecting discounts, rebates, chargebacks, to all classes except FSS." [5] Ex. A., Interrogatory 1(e).[6] Likewise, Plaintiffs' Exhibit B[7] to the instant motion defines ASP as WAC minus discounts given to wholesalers and minus other rebates or special contract terms for customers. *See* Pls.' Ex. B. Thus, by all accounts, the ASP of any given drug contemplates at least two levels of price incentives -- discounts to wholesalers *plus* a second level of after-the-sale reductions, including rebates, chargebacks or other incentives. Accordingly, ASP has no value as a reliable indicator of AWP or the alleged AWP spread.

Moreover, even when price reductions to wholesalers are factored into the determination of the average wholesale price, such price reduction does not establish ASP. Rather, as Plaintiffs' Exhibit B demonstrates, WAC minus discounts to wholesalers equals Average Manufacturing Price ("AMP") -- not ASP. *See* Pls. Ex. B. Thus, ASP, with its second set of

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[5] "FSS" is nowhere defined in the Omnibus Requests or in the ASP Requests. However, "FSS" is the common abbreviation for the Federal Supply Schedule.

[6] In their ASP Requests, Plaintiffs incorporate by reference this and all other definitions contained in their Omnibus Requests. *See* Plaintiffs' Request for Production to Defendants Regarding HHS ASPs at 1, Definition No. 1.

[7] Plaintiff's Exhibit B is a document produced in this litigation by Defendant Johnson & Johnson, which Plaintiffs' contend is "a telling document" that provides "transparency . . . as to the current spread and how it was calculated." Pls.' Mem. at 2.

discounts in the form of after-the-sale rebates and customized contract term incentives (*e.g.* volume discounts, prompt payment discounts) (see Pls.' Mem. at 2) has no relevance whatsoever in determining the average *wholesale* price or corresponding "spread" for any given drug. Accordingly, the Court should deny Plaintiffs' Motion to Compel in its entirety.

III. CONCLUSION

As the foregoing demonstrates, Plaintiffs' Motion to Compel must fail. Plaintiffs ASP Requests are unduly burdensome because Plaintiffs have not and cannot establish the relevancy of the information they seek. Indeed, Plaintiffs have not alleged the relevance of ASP in their Complaint or in prior motions to dismiss. Accordingly, Sicor respectfully requests that the Court deny Plaintiffs' Motion to Compel in its entirety.

Dated July 19, 2004

Respectfully submitted:

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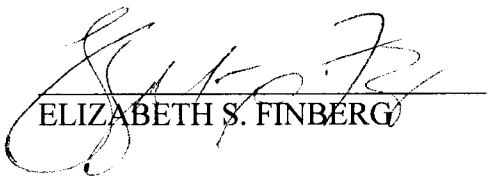
CERTIFICATE OF SERVICE

I , Elizabeth S. Finberg, an attorney, hereby certify that on July 19, 2004, I caused a true and correct copy of the foregoing Defendant Sicor Inc. and Sicor Pharmaceuticals, Inc.'s Opposition to Plaintiffs' Motion to Compel HHS ASP Documents to be served on all counsel of record electronically via Verilaw Technologies, pursuant to Section D of Case Management Order No. 2.



ELIZABETH S. FINBERG